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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------|------------------|
| 09/898,743 | 07/03/2001 | Krassen Dimitrov | P-IS 4548 | 3666 |
| 23601 | 7590 | 08/23/2004 | EXAMINER | |
| CAMPBELL & FLORES LLP 4370 LA JOLLA VILLAGE DRIVE 7TH FLOOR SAN DIEGO, CA 92122 | | | CHUNDURU, SURYAPRABHA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1637 | |

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/898,743 | DIMITROV, KRASSEN | |
| | Examiner | Art Unit | |
| | Suryapraba Chunduru | 1637 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 04 August 2004.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-15 and 78-84 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-15 and 78-84 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____.

DETAILED ACTION

1. Acknowledgement is made for the request to establish continued prosecution application (RCE) filed on August 4, 2004. The request for RCE is accepted and is established with the status of the application as follows:
 - a. the filling date of this RCE is established as July 3, 2001;
 - b. Claims 1-15, 78-84 are pending. Claims 16-77 are cancelled. Claims 1, 7, 78 are amended.
2. Applicants' response to the earlier office action filed on August 4, 2004 is entered and reconsidered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15, 78-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims 1, 7 and 78 recite “ attachment of label monomers of said unique labels to nucleotides in a 1:1 correspondence”. The meets and bounds of the claims is unclear and indefinite because it is not clear whether each nucleotide in a nucleic acid molecule is labeled with a unique label or a unique label is attached to a nucleotide in a nucleic acid molecule comprising several nucleotides. The Fig. 1 of the instant specification discloses that a unique label is attached to a stretch of nucleotides and it is not clear whether the label is confined to a single nucleotides are several nucleotides together.

Claim Rejections - 35 USC § 102

Art Unit: 1637

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

A. Claim 1, 3-4, 6-7, 10,12 are rejected under 35 U.S.C. 102(b) as being anticipated by Luehrsen et al. (J Histochem Cytochem., Vol. 48(1), pp. 133-145, January, 2000).

Luehrsen et al. teach a diverse population of labels of claim 1 and 7, comprising about thirty or more unique labels (16-64 labels), wherein each of said unique label is bound to a nucleic acid molecule or nucleic acid probe (see page 133, summary, page 134, col. 1, paragraph 3, col. 2, paragraph 2 under materials and methods section) by attachment of label monomers (happens) of unique labels to nucleotides in a 1:1 correspondence (each label is attached to a nucleotide of said nucleic acid molecule, indicating 1:1 correspondence).

With regard to claims 3-4, 6, 10, 12, Luehrsen et al. teach said diverse population comprises unique labels selected from 40-60 labels which are selected from biotin, digoxigenin or fluorescein labels (see page 133, summary, page 137, col. 2, lines 12-22).

Thus the disclosure of Luehrsen et al. meets the limitations in the instant claims.

b. Claim 1-10, 12-15, 78-84 are rejected under 35 U.S.C. 102(e) as being anticipated by Mirkin et al. (USPN. 6,361,944).

Mirkin et al. teach claim 1, 7, 83, a diverse population of labels, or labeled probes and kit comprising the said labels, comprising at least two unique labels (nanoparticle labeled with fluorescent labels) (at least two indicates more labels) (see col. 15, line 7-15, Figs. 17A-E, col. 28, lines 20-34, col. 29, lines 3-60), wherein each said unique label is bound to a nucleic acid molecule (oligomer) by attachment of label monomers of said labels to nucleotides in 1:1 correspondence (see Fig. 17A-C);

With regard to claim 2, 8, Mirkin et al. teach said unique label comprise about same unit signal (color intensity) or multiple signal intensities (see col. 16, line 64-67, col. 17, line 1-7);

With regard to claim 3, 9, Mirkin et al. teach that said unique labels comprise mixture of two or more different labels (see col. 22, lines 40-45, col. 29, line 3-60);

With regard to claim 4-5, 10, 81, 84, Mirkin et al. teach said unique labels comprise at least two types of labels, (which indicates two or more labels – could be about 40 or more) (see col. 16, line 64-67, col. 17, line 1-7);

With regard to claim 6, 12, 82, Mirkin et al. teach that said labels comprise fluorescent labels (see col. 29, line 3-60);

With regard to claims 7, 13, Mirkin et al. teach a diverse population of unique probes comprising target specific nucleic acid probes and each probe is attached to a unique label (see col. 28, lines 20-34, Fig. 24, col. 15, line 50-59);

With regard to claim 14, Mirkin et al. teach that the method comprises two types of nucleic acids bound to unique labels (see col. 9, lines 45-55, col. 27, lines 22-57);

With regard to claim 15, 79-80, Mirkin et al. teach that divers population further comprises a specifier (universal probe), a dendrimer or a genedigit (see Fig. 25B, col. 15, line 60-65, col. col. 40, lines 52-65, col. 28, lines 55-67);

With regard to claim 78, Mirkin et al. teach a kit comprising a set of genedigits (oligomers) and a unique set of labels bound to a nucleic acid (see col. 38, lines 14-23).

Thus the disclosure of Mirkin et al. meets the limitations in the instant claims.

B. Claim 1, 4, 6, 10-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Krantz et al. (USPN. 6,277,583).

Krantz et al. teach a diverse population of labels of claim 1, comprising one or more unique labels (affinity labels), wherein each unique label monomer is bound to a nucleotide of a nucleic acid molecule (oligomer) (see col. 4, lines 3-7, line 59-65);

With regard to claim 4, 10-11, unique labels having diversity selected from a group consisting of at least about 100 to 10,000 or more members (see col. 6, line 46-50);

With regard to claim 6, the labels are fluorescent (see col. 9, line 43-50).

Thus the disclosure of Krantz et al. meets the limitations in the instant claims.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782 . The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru
August 19, 2004


JEHANNE SITTON
PRIMARY EXAMINER
8/19/04